

Tissue Chip for Drug Screening

NIH-DARPA-FDA Collaboration to Help Predict Drug Safety

Program Overview

The National Institutes of Health, in collaboration with the Defense Advanced Research Projects Agency (DARPA) and U.S. Food and Drug Administration, is leading an initiative to improve the process for predicting whether drugs will be safe in humans. The goal is to develop human tissue chips that accurately model the structure and function of human organs, such as the lung, liver and heart. Once developed, researchers can use the tissue chips to test drug candidates and help predict safety in human studies more rapidly and cost-effectively than current methods.

More than 30 percent of promising medications have failed in human clinical trials because they are determined to be toxic despite promising pre-clinical studies in animal models.¹ Tissue chips may enable scientists to predict more accurately the toxic effects of potential therapeutic candidates because they use human cells capable of mimicking an organ's structure and function.

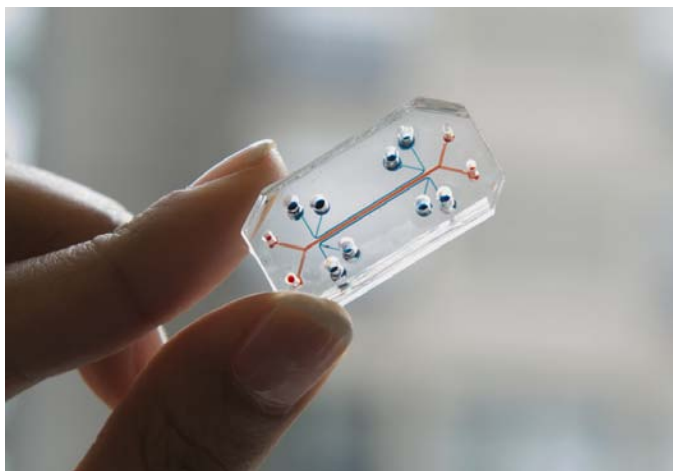


Image courtesy of the Wyss Institute.

The [NIH Tissue Chip for Drug Screening](#) initiative marks the first interagency collaboration launched by NIH's newly created center, the National Center for Advancing Translational Sciences (NCATS). NIH's Common Fund and National Institute of Neurological Disorders and Stroke led the trans-NIH effort to [establish the program](#).

Improving Predictive Systems for Drug Safety

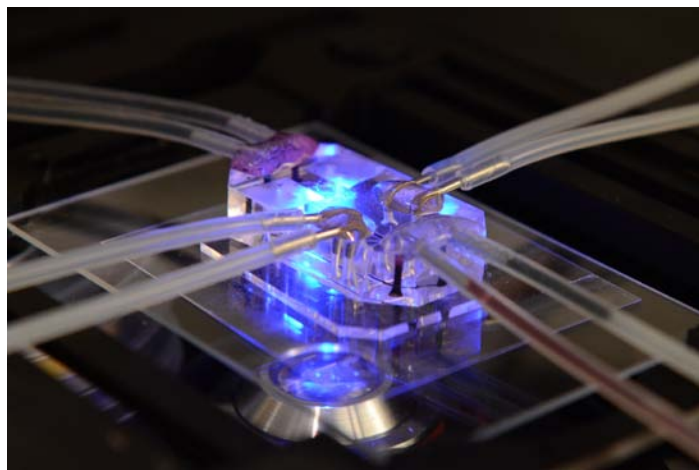


Image courtesy of the Wyss Institute.

In July 2012, NIH [issued](#) 17 awards, 10 of which will support studies to develop 3-D cellular microsystems that represent a number of human organ systems. These bio-engineered devices will be functionally relevant and also accurately reflect the complexity of the tissue of origin, including genomic diversity, disease complexity and pharmacological response. The additional seven awards will explore the potential of stem and progenitor cells to differentiate into multiple cell types that represent the cellular architecture within organ systems. These could act as a source of cells to populate tissue chips.

In addition to focusing on organ systems, some of the awarded researchers will develop tissue microsystems that target specific health conditions, such as cardiovascular disease, cancer, degenerative arthritis and gastrointestinal disease.

¹ Kola, I., Landis, J. Can the pharmaceutical industry reduce attrition rates? *Nat Rev Drug Discov*, 2004;3(8):711–715.

In fiscal year 2012, NCATS contributed about \$9 million to the NIH tissue chip awards. In addition, the NIH Common Fund provided \$4 million. NIH anticipates committing up to \$70 million over the next five years for the Tissue Chip for Drug Screening initiative. For more details about the NIH awards, visit ncats.nih.gov/tissue-chip-awards2012.html.

The NIH and DARPA programs will be coordinated closely. For example, DARPA has entered into cooperative agreements with two of the NIH recipients (the Wyss Institute at Harvard University and the Massachusetts Institute of Technology) to develop engineering platforms capable of integrating 10 or more organ systems. After two years, the NIH and DARPA awardees will work together to integrate the tissue microsystems on the engineering platforms.

Throughout the program, the FDA will help explore how this new technology might be used to assess drug safety prior to approval for first-in-human studies.

About NCATS and NIH

NCATS aims to catalyze the generation of innovative methods and technologies that will enhance the development, testing and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions. By improving the process by which diagnostics and therapeutics are developed, NCATS strives to make translational science more efficient, less expensive and less risky. In this way, NCATS is complementing — not competing with — the work of the private sector and other NIH Institutes and Centers. Visit ncats.nih.gov to learn more.

NIH, the nation's medical research agency, includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. NIH is the primary federal agency conducting and supporting basic, clinical and translational medical research, and is investigating the causes, treatments and cures for both common and rare diseases. Visit www.nih.gov.

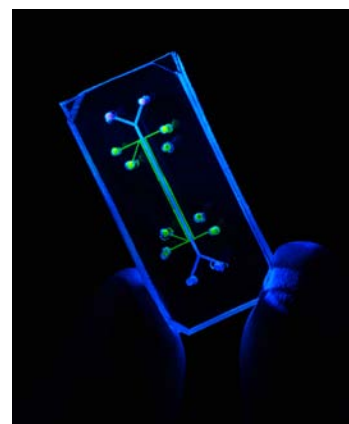


Image courtesy of the Wyss Institute.

For More Information

Contact

NCATS Communications at 301-435-0888 or info@ncats.nih.gov.

Website

Visit NCATS online at ncats.nih.gov/tissue-chip.html.

Award Information

To learn more about the funded projects and the Tissue Chip for Drug Screening Program, visit ncats.nih.gov/tissue-chip-awards2012.html.

Frequently Asked Questions

To view answers to frequently asked questions, visit ncats.nih.gov/tissue-chip-faq.html.